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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,227	07/29/2003	Subhas Kundu	A4072.0024/P024-A	4761

24998 7590 12/13/2005

DICKSTEIN SHAPIRO MORIN & OSHINSKY LLP  
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EXAMINER

YEBASSA, DESTA LETTA

ART UNIT PAPER NUMBER

1615

DATE MAILED: 12/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/628,227	KUNDU ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Desta L. Yebassa	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 154-264 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 154-264 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____.  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                                    |

### **DETAILED ACTION**

Acknowledgment is made for the information disclosure statement (IDS) filed on 11/05/2003. Receipt is also acknowledged of the oath or declaration filed on 07/29/2003.

### ***Election/Restrictions***

- Restriction to one of the following inventions is required under 35 U.S.C. 121:
- The inventions are distinct, each from the other because of the following reasons:
- Group I. Claim(s) 154-187 are drawn to a method for forming a flocculated suspension of megestrol acetate, wherein one or more of the steps is performed at a temperature of at least about 25C, classified in class 424, subclass 489.
- Group II. Claim(s) 188-221 are, drawn to a method for forming a flocculated suspension of megestrol acetate, wherein one or more of the steps uses high shear mixing for at least about one hour, classified in class 424, subclass 489.
- Group III. Claims 222-264 are drawn to a method for forming a flocculated suspension of megestrol acetate, wherein the batch weight is adjusted to achieve about 40 mg megestrol acetate per ml, classified in class 424, subclass 489.

Inventions of Group I, Group II, are Group III is unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have

Art Unit: 1615

different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case each Group of invention has different process and steps i.e. in Group I, the steps is performed at a temperature of at least about 25C, in Group II, the steps uses high shear mixing for at least about one hour, and in Group III, the batch weight is adjusted to achieve about 40 mg megestrol acetate per ml, and therefore, they are unrelated inventions.

Because these inventions are distinct for the reasons given above and the search required for group I, are not required for group II, and group III, restriction for examination purposes as indicated above is proper. Furthermore, a reference reading on group I may not be applicable to group II, and group III etc.

Due to the complex nature of the Restriction/Election requirement, a telephone call to the applicant requesting a verbal election was not made.

### **Telephonic Inquiry**


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Desta L. Yebassa whose telephone number is 571-272-8511. The examiner can normally be reached on Monday to Friday 8.00 am –6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Desta L. Yebassa, PhD  
Patent Examiner  
Art Unit 1615

  
THURMAN K. PAGE  
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TECHNOLOGY CENTER 1600